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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/783,522	02/20/2004	Roy Lurie	MWS-109	7481
959	7590	10/02/2006	EXAMINER	
LAHIVE & COCKFIELD 28 STATE STREET BOSTON, MA 02109			WHALEY, PABLO S	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 10/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/783,522

Applicant(s)

LURIE ET AL.

Examiner

Pablo Whaley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 37-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 11/8/2004 and 5/15/2006.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

D7ETAILED ACTION*APPLICANT'S ELECTION*

Applicant's election with traverse of Group I (claims 1-36) in the reply filed on 7/31/06 is acknowledged. The traversal is on the assertion that Groups I and II are related, overlapping in scope, and share the same classification. Applicant's assertion that biological processes may be described with chemical reactions at the most basic level is noted. However, in general the literature describing biological processes and chemical reactions (e.g. pharmaceutical compounds, non-biological and biological, chemical structures, etc.) are not co-extensive. Furthermore, Groups I and II are directed to methods for modifying models of biological processes and chemical reactions which are not limited to the same experimental platforms or analysis environments. After considering the applicant's points in full, burden of search is maintained as the examination process requires a search of non-patent literature, U.S. patent publications, U.S. patents, as well as foreign patent literature. The requirement is still deemed proper and is therefore made FINAL. Claims 37-50 are hereby withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 7/31/2006.

CLAIMS UNDER EXAMINATION

An action on the merits of claims 1-36 follows.

INFORMATION DISCLOSURE STATEMENT

The information disclosure statements filed 11/8/2004 and 5/15/2006 have been considered in part. In the IDS of 11/8/04, the Dialog Search results are not a publication. In the IDS of 5/15/06, we do not consider International Search Reports, as they do not have a publication date.

DRAWINGS

Drawings filed 2/20/2004 have been accepted.

INFORMALITIES

The specification is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on page 20, and elsewhere. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The specification also contains numerous Trademarks, for example, on page 9 and elsewhere. It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

CLAIM REJECTIONS - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-11 and 28-36 are rejected under 35 U.S.C. 101 because these claims are drawn to non-statutory subject matter. Claims 1-9 and 28-36 are directed to systems comprising a simulation engine and an analysis environment in communication with said simulation engine. The system is not limited to comprise any hardware element or combination of software and hardware such that it is interpreted to be a physical article of manufacture. Furthermore, no description or definition for said "simulation engine" or "analysis environment" is provided in the Specification such that they would be interpreted as physical elements of the "system" claimed. For these reasons, the claims are not statutory. For an updated discussion of statutory considerations with regard to non-functional descriptive material and computer-related inventions, see the Guidelines for Patent Eligible Subject Matter at 1300 OG 142, Annex IV, Nov. 22, 2005.

CLAIM REJECTIONS - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 12, and 28 recite the limitation "analysis environment." As the specification does not define or fully and completely describe "environment," it is unclear as to the metes and bounds intended by applicant for the claimed "analysis environment" such that one skilled in the

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art would know whether this is a search engine, an operating system, or something else. Clarification is requested. The Examiner has interpreted this limitation broadly for purposes of applying prior art.

Claims 1, 12, 22, and 28 recite the limitation "biological process responsive to experimental results" in the preamble. It is unclear in what way said biological process is "responsive" to said experimental results. Clarification is requested.

Claims 1, 22, and 28 recite the limitation "experimental results generated by an in situ experiment conducted on a experimental platform" in the preamble. It is unclear if the functional limitation "generated by an in situ experiment..." is intend intended to be an actual method step, a further limitation of the claimed method, or otherwise. Clarification is requested.

Claims 1, 12, 22, and 28 recite the limitation "experimental platform" in the preamble. It is unclear whether said "platform" is intended to be a physical object, an experimental setup, or otherwise. Clarification is requested. The Examiner has interpreted this limitation broadly for purposes of applying prior art.

Claim 1 recites the functional limitation "said analysis environment gathering data...and comparing the result." It is unclear whether said "gathering" and "comparing" are intended to be active method steps or some sort of limitation of the said analysis environment. If the latter, it is unclear what structural or physical limitation of the claimed system is intended by the applicant. Clarification is requested.

Claims 4 and 15 recite the limitation "generates an event." It is unclear whether said "event" is intended to be a physical event, non-physical event, or otherwise. Clarification is requested. The Examiner has interpreted this limitation broadly for purposes of applying prior art.

Claims 5, 16, and 32 recite the limitation "modeling environment." As the specification does not define or fully and completely describe "environment," it is unclear as to the metes and bounds intended by applicant for the claimed "modeling environment." Clarification is requested. The Examiner has interpreted this limitation broadly for purposes of applying prior art.

Claim 12 is directed to a method for "modifying a model of a biological process" in the preamble. However, claim 12, step (e), results in "comparing...the generated expected result to data gathered." Therefore it is unclear in what way the instant claim achieves the purpose of the preamble, as parent claim does not recite any step directed to "modification" of a model. Clarification is requested.

Claim 22 recites the limitation "the chemical experiment." There is lack of antecedent basis for this limitation. It is noted that claim 22 previously recites an *in situ* experiment. Correction is requested.

CLAIM REJECTIONS - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-9, 11, 22, 23, 25-27, 28-30, and 32-36 are rejected under 35 U.S.C. 102 (b) as being anticipated by Goryanin et al. (Bioinformatics, 1999, Vol. 15, No. 9, p.749-758).

Goryanin et al. teach a system and computer program (*DBsolve 5.00*) for mathematical simulation and analysis of cellular metabolism and regulation. Goryanin et al. teach the following aspects of the instantly claimed invention:

- Analysis models (i.e. simulation engines) model metabolic pathways, receive input, generate output, and display results via the operably connected model designer [Fig. 1 and Fig. 3], as in instant claims 1-3, and 5, and instant claims 28-30, and 32.

- Fitter/Optimizer environment (i.e. analysis environment) in communication with said simulation engine and comparing model data to experimental data for optimization [Fig. 1] and [p.753, Col. 2, ¶ 2], as in instant claims 1 and 28.
- Fitter/Optimizer generates an optimized curve (i.e. event) when the difference between experimental and theoretical data points is calculated according to an absolute value [p.755, Col. 1, ¶ 1], which equates to generating an event as in instant claim 4.
- Model Designer (i.e. modeling environment) in communication with said analysis models and Fitter/Optimizer [Fig. 1] comprising constructing a model and a GUI for accessing the model and accepting user commands [Fig. 2], as in instant claims 5-9 and 32-36.
- Input of experimental data for refining the biological model [p.753, Col. 2, ¶ 2], as in instant claims 1 and 9. Furthermore, the use of experimental data is implicitly a teaching for data gathered from “experimental platform” and/or “experimental device”, as recited in instant claims 1, 11, 28, and 35, as experimental data is inherently obtained from an experimental devices.
- *DBsolve 5.00* is computer-readable program (i.e. article of manufacture) functionally operating on a computer system to carry out the above method steps, therefore claims 22, 23, and 25-27, which recite identical limitations as above, are also anticipated.

Claims 1-2 and 10 are rejected under 35 U.S.C. 102 (b) as being anticipated by DelaFuente et al. (Proceedings of the Second International Conference on Systems Biology, Pasadena, California, 2001, p. 213-221).

DelaFuente et al. teach a method for reverse engineering gene regulatory networks from microarray gene expression data using a computer system [Abstract]. In particular, the method

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of DelaFuente et al. comprises a computer model (i.e. simulation engine) for generating expected results, and a software analysis environment for gathering and comparing theoretical and experimental values [Table 1] and [p.216, Col. 2, ¶ 2], and displaying results, as required by the system of instant claims 1 and 2. DelaFuente et al. also teach measuring and analysis of gene expression ratios using microarray or gene chips [p.215, Col. 2, ¶ 1], as in instant claim 10.

Claims 12-19 and 21 are rejected under 35 U.S.C. 102 (e) as being anticipated by Potts et al. (US Pat. No. 6,882,940; Filed Aug. 10, 2001).

Potts et al. teach methods for predicting a hypoglycemic event in a subject [Abstract]. More specifically, the method of Potts et al. comprises the following aspects of the instantly claimed invention:

- Methods for extracting glucose from a subject glucose into reservoirs and techniques and/or devices for generating glucose data [Col. 3, lines 25-35], which equates to conducting an in situ experiment and gathering data, as in instant claim 12.
- Glucose monitoring system comprising a sensing mechanism for obtaining measured data values and microprocessors for generating predicted glucose measurement values (i.e. expected results) [Col. 3, lines 40-60], as in instant claim 12. Furthermore, the system provides for the display of data, operative connection of its units, wireless transmission of data [Col. 18, lines 5-25], as in instant claims 13, 14, and 18.
- Comparing predicted glucose measurement values to threshold glucose values [Reference claims 1 and 25], as in instant claim 12.

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- Alert signal (i.e. event) generated when glucose amount is outside of the predetermined range of values [Co. 7, lines 20-23], as in instant claim 15.
- Glucowatch prediction system (i.e. modeling environment) allowing for user-settable threshold levels [Col. 13, lines 20-25] and comprising an LCD screen and user interface [Col. 16, lines 60-65], as in instant claims 16-17.
- Predictive Taylor-Series expansion model for adjusting glucose values to predict future values [Equation (7), Reference claim 7], which is a teaching for generating a refined model as in instant claim 19.
- GlucoWatch biographer comprising microprocessor (i.e. analyte monitoring device and display unit) for measuring and analyzing glucose levels from a subject via ionophoresis [Col. 7, lines 15-23], which is a teaching for in situ experimentation and a device as in instant claim 21.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 12, 13, 14, 20, and 21 are rejected under 35 U.S.C. 103(a) as being made obvious by DelaFuente et al. (Proceedings of the Second International Conference on Systems Biology, Pasadena, California, 2001, p. 213-221), as applied to claims 1-2 and 10, above, in view of Bubendorf et al. (Journal of Pathology, 2001, Vol. 195, p.72-79).

DelaFuente et al. teach a method for reverse engineering gene regulatory networks from microarray gene expression data using a computer system [Abstract], as set forth above. DelaFuente et al. also teach methods of displaying data, as set forth above and recited in claims 13 and 14.

DelaFuente et al. do not specifically teach the use of in situ experimentation using a microarray data and in situ experimentation, as recited in claims 12 and 20. However, DelaFuente et al. suggest that their method is very suitable to be applied to microarray technologies.

Bubendorf et al. teach a method of high-throughput in situ experimentation using tissue microarrays (TMA) technology [Abstract]. Bubendorf et al. also teach the display of in situ TMA experiments in patient samples [Fig. 5] and related data sets [Table 1], as in instant claims 12 and 20.

Thus it would have been obvious to someone of ordinary skill in the art at the time of the instant invention use the gene regulatory network model of DelaFuente et al. with the TMA data sets taught by Bubendorf et al, where the motivation would have been to significant accelerate tumor research using high-throughput in situ technologies [Bubendorf et al., Abstract], resulting in the practice of the instant claimed invention with a reasonable expectation of success. One of ordinary skill in the art would have had a reasonable expectation of successfully combining the

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data sets of Bubendorf et al. with the model of DelaFuente et al. as both teach microarray data sets and analysis.

CONCLUSION

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pablo S. Whaley

Patent Examiner
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9/27/06
Patent Examiner